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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/724,416      | 11/28/2000  | Hong Jin             | 7682-052-999        | 7604             |

20583 7590 02/25/2003

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| EXAMINER |
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LUCAS, ZACHARIAH

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1648

DATE MAILED: 02/25/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/724,416

Applicant(s)

JIN ET AL.

Examiner

Zachariah Lucas

Art Unit

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-- Th MAILING DATE of this communication appears on the cov r sheet with th correspond nc address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 19-21, 33, 34, and 41-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 22-32 and 35-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of the Application***

1. Claims 1-48 are currently pending in the application. Claims 1-16, 19-21, 33, and 34 have been withdrawn as to non-elected inventions. Claims 41-48 were added in the response filed December 5, 2002 (Amend. C). These claims read on the non-elected invention of Group VII in the Restriction requirement mailed on March 11, 2002. The claims are therefore withdrawn from examination. Claims 17, 18, 22-32, and 35-40 are under consideration and were rejected in the prior action.

2. The Art Unit location of your application, and the examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachariah Lucas in Art Unit 1648.

### ***Priority***

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows: there is no inventor in application 08/316,439, to which priority is claimed through application 09/161,122, that is also an inventor of the present application. It is noted that the applicant has requested correction of inventorship for the 09/161,122 application, requesting that David Kirkwood Clarke and Peter Palese be added as inventors to that application. However, even if this request has been granted, such does

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perfect priority as the current application does not share an inventor with the 08/316,439 application.

*Specification*

4. **(New Objection)** The amendment filed December 5, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 5 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: the incorporation by reference of the material of prior application 08/316,439. The material of this application may not be incorporated by reference into the present application as such material was not part of the present application upon filing of this application. This New Matter objection would not be resolved by the perfection of a claim of priority to the prior application.

Applicant is required to cancel the new matter in the reply to this Office Action.

*Claim Rejections - 35 USC § 112*

5. **(Prior Rejection-Withdrawn in part)** Claims 17-18, 22-32, and 35-40 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vaccines for non-human mammals, does not reasonably provide enablement for human vaccines. In view of the arguments made by the applicant, and the indications in the art that such recombinant RSV virus as are described by the claims, the rejection is withdrawn to the

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extend that the claims read on RSV particles with at least one of the identified deletions in the M2-2, NS1, NS2, or SH genes. However, claim 17 describes a vaccine composition comprising an RSV comprising the reverse complement of an mRNA coding sequence operatively linked to polymerase binding site of the RSV. The claim does not require that the virus comprise any attenuating phenotypes required by the dependant claims. In view of the fact that claim 17 reads on a vaccine composition comprising an unattenuated whole RSV virus, and that the applicant has not shown that such virus are useful as a vaccine- the applicant is not enabled for the full extent of the claimed invention. Thus, the rejection maintained for claims 17, and 36-40, and withdrawn for the other claims.

***Claim Rejections - 35 USC § 102***

6. **(Prior Rejections-Maintained)** Claims 17-18, 22-32, and 35-40 were rejected as anticipated by two references 1) Collins et al. (WO 97/12032), and 2) Murphy et al. (U.S. Patent 5,993,824). The applicant traversed both of these rejections with the same argument- i.e. an amendment to the present application claiming priority to a prior application predating these two references. As described above, the applicant has not satisfied the requirements for claiming such priority in that the applicant has not shown that the present application shares at least one inventor with the prior application. For this reason alone, the rejection may be maintained.

However, there is another reason that this traversal is not found persuasive. The application to which the applicant is attempting to claim priority does not teach the rejected subject matter. In order for an applicant to avoid a prior art rejection by claiming benefit to an

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earlier application, the applicant must show more than the fact that the priority application predates the prior art. The applicant must show that the earlier application teaches so much of the claimed invention as is taught by the prior art references. See e.g., In re Stempel, 113 U.S.P.Q. 77, at 79-81 (discussing what the applicant needs to show in a 131 affidavit in order to avoid a prior rejection). In the case presently under examination, the application to which priority is claimed teaches the development of recombinant negative strand RNA virus, and focuses on the generation of Influenza virus. See, U.S. patent 5,840,520 (patent issued from application 08/316,439), generally. There is no in depth discussion of the RSV virus until columns 42-50. More particularly, there is no descriptive support for RSV virus with deletions in, or of, the SH, NS1, NS2, or M2-2 genes at all. In view of the lack of support in the application to which the applicant intended to claim priority for the rejected claims, even if the claim for priority had been successful, it would not have avoided the art rejections.

For both of the reasons laid out above, and for the reasons of record, the rejections of claims 17, 18, 22-32, and 35-40 as anticipated by both Collins and Murphy are maintained.

***Claim Rejections - 35 USC § 103***

7. **(Prior Rejection-maintained)** Claims 17, 18, 22-32, and 35-40 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (PNAS 92:11563-11567) in view of Olmstead et al. (PNAS 83:7462-7466). The applicant has traversed this rejection for the same reasons set forth above with regards to the 102 rejections over Murphy and

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Collins. The traversal is not found persuasive for the reasons stated above. The rejection is therefore maintained for those reasons, and for the reasons of record.

***Conclusion***

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

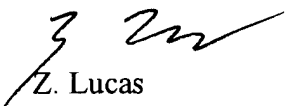
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

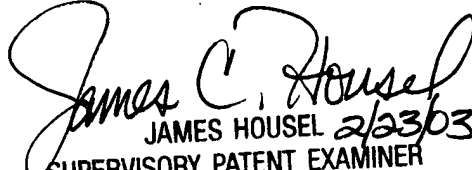
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
February 10, 2003

  
JAMES HOUSEL 2/23/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600